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(54) Guide wire unit

(57) A stylet unit suitable for stiffening a hollow electrode cable, e.g. during the cable's introduction and the anchoring of its end in the human body. The stylet unit (22) consists of a combination of a pair of flexible, coaxially arranged stylet means, viz. A tubular stylet sleeve (24, 58, 68) and an internal stylet (26, 74, 70), which can be inserted into the sleeve and whose end section (18, 66, 76) is pre-bent to one side. Both the stylet sleeve (24, 58, 68) channel and moving inner stylet (26, 64, 70) housed therein have sections or segments with non-circular cross-sections, the profile of the stylet's non-circular cross-section thereby being such, in relation to the profile of the sleeve channel's non-circular cross-section, that the stylet is kept from rotating in relation to the surrounding sleeve, at least within the parts of the sleeve in which both the stylet and the sleeve channel have interacting non-circular cross-sections. The stylet sleeve (24, 58, 68) also has a distal end section (28) which is pre-bent in a first lateral direction in relation to the stylet unit, and the inner stylet's (26, 64, 70) distal end section (18, 66, 76) is pre-bent in the diametrically opposite lateral direction.

Fig.2

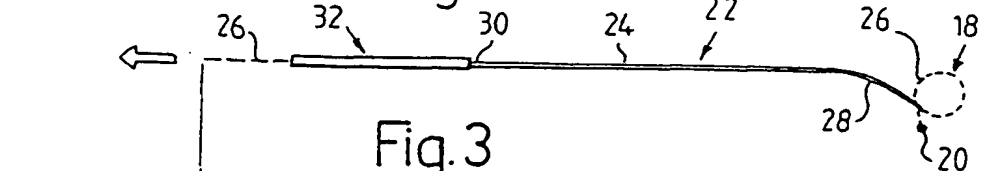
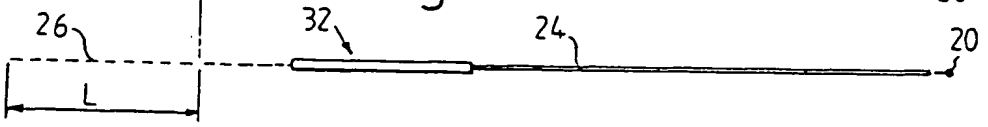


Fig.3



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Description

Field of the invention

The present invention relates to a stylet unit, which can be inserted into an elongate means with an internal longitudinal channel, such as an electrode cable for a heart stimulator, a coronary catheter or some other kind of hollow, oblong instrument, in order to stiffen the channel-equipped means and bend the distal end section of same, said stylet unit consisting of a double stylet combination comprising a flexible, tubular stylet sleeve and an inner stylet, which can be inserted into the sleeve' channel, with a distal end section pre-bent to one side.

A channel-equipped means of the aforementioned kind can e.g. be a tubular conductor used for achieving stimulation inside the human body. The channel-equipped means can either serve as the implant or be removed from the body after treatment is concluded.

Description of the prior art

A stylet unit of the present kind is especially suitable for stiffening and maneuvering a hollow electrode cable for a heart stimulator, in conjunction with introduction of the electrode cable into a patient's heart, and for anchoring the contact electrode (electrode head) on the distal end of the cable in a cavity in the heart. Introduction of such an electrode cable into the heart is usually performed through a suitable vein, and the contact electrode can be anchored in the right ventricle or atrium. The stylet unit temporarily housed inside the hollow electrode cable extends through the cable's central channel from the cable's proximal end (which is subsequently connected to the heart stimulator) to its distal end on which the contact electrode is located.

Especially in the anchoring of a contact electrode in the heart's atrium, a stylet unit is appropriately used with which the distal end section of the used electrode cable can be given a suitable J shape, simplifying introduction of the end section into the atrial auricle and anchoring of the contact electrode in the trabeculae of the atrial auricle. After the contact electrode has been anchored at the desired site in the heart, the stylet is withdrawn from the electrode cable.

US A 5 170 787 describes and shows (see FIG. 2 in the patent document) a stylet unit consisting of a double stylet combination consisting of a flexible, tubular stylet sleeve holding an inner stylet which is moveable in the sleeve's central channel. At the proximal end of this known stylet unit, there is an operating handle with which the sleeve and inner stylet can be moved in relation to each other to retract the stylet's pre-bent distal end section into the distal end section of the surrounding sleeve or deploy the pre-bent distal end section outside the opening of the sleeve's end section into the central channel of the distal end section of the surrounding electrode cable, thereby imparting the desired bent shape to the end of the cable.

US A 4 136 703 describes and shows another example of a stylet unit, devised as a double stylet combination, for an electrode cable, containing an inner stylet with a pre-bent distal end section. However, these known types of stylet units, devised as double stylet combinations, do not ensure that the stylet unit (and, accordingly, the surrounding electrode cable) is completely straight when the inner stylet's pre-bent distal end section is fully retracted inside the stylet sleeve.

Summary of the invention

One first main object of this invention is to achieve a stylet unit devised to form a completely straight double stylet combination when the inner stylet (whose distal end section is pre-bent to one side) has been retracted into the stylet sleeve so far that the distal end section of the stylet is also inside the stylet sleeve. When this pre-bent end section is deployed outside the opening of the stylet sleeve, it bends the corresponding section of the surrounding channel-equipped means which (as noted above) can be a hollow cable, a catheter or some other elongate instrument displaying flexural stiffness.

A second main object of this invention is to achieve a stylet unit in which the stylet sleeve channel and the moving inner stylet therein are devised so the stylet is kept from rotating in relation to the surrounding sleeve within at least a longitudinal section and/or in the area of at least a local section of the sleeve channel, at least at a given axial position for the stylet in relation to the stylet sleeve.

An additional object of this invention is to achieve a stylet unit which is designed so the means or bodies which prevent undesirable rotation of the stylet in relation to the surrounding stylet sleeve do not cause excessively high contact pressure and, accordingly, any operating force increasing friction between the stylet and the interior of the sleeve channel.

Another object is to achieve a stylet unit which is devised so two or more longitudinal sections of the stylet inside the stylet sleeve's central channel are prevented from rotating in relation to the stylet sleeve, thereby making the stylet unit reliably maneuverable from the unit's proximal end.

Yet another object is to achieve a stylet unit which displays a very pronounced J shape when the inner stylet's distal end section has been fully deployed outside the opening of the stylet sleeve.

The problems related to these objects can be solved according to this invention when a stylet unit of the aforementioned kind has the distinctive features set forth in the characterizing part of patent claim 1.

Preferred embodiments of the stylet unit according to the invention can also display the features set forth in the dependent patent claims.

Thus, the most distinctive feature of the stylet unit according to the invention is that the stylet sleeve has

at least one longitudinal section or segment within which the sleeve channel has a non-circular cross-section, and the inner stylet, which can move inside the stylet sleeve, has at least one longitudinal section with a non-circular cross-section, and the profile of the stylet's non-circular cross-section is such, in relation to the profile of the stylet's sleeve's non-circular channel cross-section, that the stylet is prevented from rotating in relation to the surrounding sleeve in the areas of the sleeve in which the stylet and the stylet channel have interacting non-circular cross-sections.

Within the scope of the invention in its aforementioned general form, a plurality of different "combinations" of interacting parts and/or areas with non-circular cross-sections for the stylet sleeve channel and the stylet insertable into same are also conceivable.

The stylet sleeve could e.g. have a first longitudinal section in which the channel has a circular cross-section and a subsequent, second longitudinal section in which the channel has a non-circular cross-section, the inner moving stylet, which can be inserted into the stylet sleeve, having a non-circular cross-section for most of its length. An alternative embodiment, the stylet sleeve channel can have a non-circular cross-section over most of the length of the sleeve, while the inner stylet has a first longitudinal section with a non-circular cross-section, a subsequent second longitudinal section with a circular cross-section and, finally, a third longitudinal section with a non-circular cross-section.

From the manufacturing point of view, however, it would be preferable for both the stylet channel and the moveable inner stylet to have a non-circular cross-section over most of their lengths, preventing the stylet from rotating, in relation to the surrounding sleeve, over all of its length.

The stylet sleeve can appropriately have a distal end section which is pre-bent in a first lateral direction in relation to the stylet unit, whereas the distal end section of the inner stylet is pre-bent in the diametrically opposite direction.

In other words, it is essential for both the stylet and surrounding stylet sleeve channel to have the same interacting non-circular cross-sectional shape, at least within one or more interacting segments, areas or sections. The stylet's and sleeve's pre-bent end sections are then preferably located on the same plane on which the midline of the stylet sleeve channel is also located.

A stylet unit of the kind described above ensures that the outward, lateral bending of the stylet sleeve, caused by the inner stylet's pre-bent distal end section when retracted into the sleeve, is compensated for and canceled out by the lateral outward bending, produced by the stylet sleeve's own pre-bent distal end section, in the diametrically opposite direction. In this manner, the stylet unit can be made to display a straight distal end section when the end section of the inner stylet is fully retracted into the end section of the sleeve.

To ensure that both lateral outward bends (i.e. the bend of the inner stylet and the sleeve's own preset outward bend) ends up on the same plane, thereby completely canceling out each other, there must be no internal rotation between the inner stylet and surrounding sleeve in the respective bent area. Any such rotation between the stylet and sleeve would cause the pre-bent distal end section of the inner stylet to produce uncontrolled lateral outward bending or unpredictable bending of the surrounding sleeve. The stylet sleeve's and the stylet's interacting, non-circular cross-section according to the invention prevents any such uncontrolled bending and ensures "stable" interaction between because the stylet automatically assumes a stable position corresponding to its lowest energy state.

Both the distal end section of the stylet sleeve and the distal end section of the stylet are appropriately pre-bent with an approximately constant bending radius, the stylet's bending radius however being much smaller than the sleeve's bending radius. The sleeve's pre-bent end section can appropriately cover a radian less than 90°, preferably not more than 45°. The stylet's pre-bent end section can have a curve length corresponding to a complete bending turn, whereby the pre-bent end section acquires the shape of a closed loop.

With an appropriate choice of curvature radii, curve lengths and flexural stiffnesses for the stylet sleeve's and inner stylet's pre-bent end sections, the stylet unit can be kept completely straight, when the stylet's pre-bent end section is completely retracted into the sleeve's distal end section.

One of the inherent difficulties, especially when a stylet unit for medical purposes is involved, is to master the special construction and strength problems posed by the very small dimensions of the inner stylet and its surrounding stylet sleeve and the dimensional relationship of the stylet/sleeve respectively.

At the same time as the stylet unit's dimensions and flexibility are governed by the flexibility needed for the unit to be able to follow the physiological and anatomical limitations encountered during the introduction of an electrode cable or catheter into the human body, the diameter of the inner stylet must not be too small, and the stylet (with its exposed, pre-bent distal end section) must still be capable of bending the enclosing, hollow cable or catheter. A stylet diameter on the order of 0.20-0.25 mm may be appropriate, with a external sleeve diameter on the order of 0.30-0.45 mm is an example of diameters for the inner stylet and associated stylet sleeve (i.e. a stylet unit designed for an electrode cable).

The inner stylet's non-circular profile is appropriately the same as the corresponding, interacting non-circulating cross-sectional profile of the stylet channel, and the play, or tolerance, between these interacting components should appropriately amount to at least 0.02 mm to ensure that relative movement between the inner stylet and the surrounding sleeve can take place without problems and with reasonable friction resistance.

A plurality of different non-circular cross-sectional profiles are conceivable of the respective interacting sections, areas or segments for the inner stylet and sleeve channel. An oval, elliptical or polygonal shape, preferably with somewhat rounded corners, are examples.

With a stylet unit according to the invention, the distal end section of the stylet unit can be made to display e.g. a U-shaped or J-shaped bends when the stylet's pre-bent end section is fully deployed, outside the stylet sleeve's corresponding distal end section.

The invention also comprises an elongate, tubular means which is a hollow electrode cable with an interior stylet unit of the kind cited above. When the stylet unit has been inserted as far as possible into the electrode cable's channel and the inner stylet's distal end section is exposed and deployed outside the style sleeve's distal end section, the bent distal end section of the electrode cable plus the straight part of the cable acquire a fish hook-like J shape, the electrode cable's distal end section being equipped with a contact electrode running essentially parallel to the said straight part of the cable towards the cable's proximal end which is designed for connection to a heart stimulator or pacemaker after the electrode cable has been introduced into a patient's heart, the contact electrode has been anchored in a cavity of the heart and the stylet unit has been withdrawn from the electrode cable.

Description of the drawings

The invention will now be exemplified, described and explained in greater detail below, referring to the attached drawings showing, in an elucidatory fashion but not to scale, several preferred embodiments of a stylet unit and an electrode cable equipped with such a unit according to the invention.

FIG. 1 shows a highly schematic view of a known double stylet combination intended for stiffening and bending an electrode cable (not shown);
FIG. 2 shows a first stylet unit according to the invention with a pre-bent distal end section which has not yet been retracted into the stylet sleeve;
FIG. 3 shows a stylet unit according to FIG. 2 with a stylet end section retracted into the stylet sleeve;
FIG. 4 shows the stylet unit's inner stylet according to FIGS. 2-3;
FIG. 5 shows the stylet unit's stylet sleeve according to FIGS. 2-3;
FIG. 6 shows a hollow electrode cable with an inserted stylet unit with a distal stylet end section deployed outside the stylet sleeve;
FIGS. 7a, 7b, 7c, 7d and 7e show examples of possible cross-sections, of a stylet unit according to the invention;
FIGS. 8a and 8b show an end section of a known stylet unit with the inner stylet unit's pre-bent end section in the deployed, exposed position and in the retracted position inside the sleeve respectively;
FIGS. 9a and 9b shows the distal end section of a stylet unit according to the invention with the pre-bent distal end section of the inner stylet in the deployed, exposed position and in the retracted position inside the sleeve respectively;
FIG. 10 is a highly schematic view showing the way an electrode cable, with an inserted stylet unit might conceivably bend while being advanced to a patient's heart;
FIG. 11 shows an example of a stylet sleeve for a second stylet unit according to the invention;
FIG. 12 shows an inner stylet designed to be movingly arranged inside the stylet sleeve shown in FIG. 11;
FIG. 13 shows an example of a stylet sleeve for a third stylet unit according to the invention;
FIG. 14 shows an inner stylet designed to be movingly arranged inside the stylet sleeve shown in FIG. 13;
FIG. 15a schematically depicts a first stage in the fabrication of a stylet of the kind shown in FIG. 14;
FIG. 15b depicts a second stage in the fabrication of the stylet according to FIG. 14;
FIG. 15c depicts a third stage in the fabrication of a stylet according to FIG. 14; and
FIG. 15b depicts a fourth and final stage in the fabrication of a stylet according to FIG. 14;
FIG. 16 shows in axial longitudinal section a stylet sleeve for a further embodiment of the stylet unit according to the invention;
FIG. 17 shows in axial longitudinal section a stylet sleeve for another embodiment of the stylet unit according to the invention;
FIG. 18 shows in lateral view an inner stylet wire adapted to be displaceably arranged in the stylet sleeve according to either FIG. 16 or FIG, 17; and finally,
FIG. 19 shows on a larger scale than FIG. 18, the transition region, located within circle R in FiG. 18, between the inner stylet's circular and non-circular cross-sections.

Description of the preferred embodiments

FIG. 1 schematically depicts a known stylet unit which is a double stylet design consisting of a flexible, tubular stylet sleeve 4 and an inner stylet 6 arranged to move freely inside the sleeve's 4 channel. The stylet sleeve 4 has a proximal end 8 and a distal end 10, and the stylet 6, which has a proximal end 14 and a distal end 16, can be moved back and forth inside the sleeve 4 in the latter's axial direction 12. Relative movement between the tubular sleeve 4 and the inner stylet 6 is usually achieved with a manipulation and holder means (not shown at the proximal end 8 of the sleeve 4. Here, a holder means could be attached to the stylet sleeve

4, and a gripping means (handle could be attached to the stylet 6, making it possible to move the stylet in relation to the sleeve when the holder means is kept still.

The relative movement of the inner stylet and the surrounding sleeve could, of course, also be achieved by keeping the stylet 6 still and moving the sleeve 4.

In the area before its distal end 16, the inner stylet 6 has a pre-bent distal end section 18 shaped like a semicircle. The distal end 16 of the stylet 6 is also equipped with a small end ball 20 (see the magnified view in the circle S), whose diameter is somewhat larger than the diameter of the stylet sleeve 4 channel, to keep the distal end 16 of the stylet 6 from being inadvertently retracted into the sleeve 4. And the risk of penetration of the surrounding electrode cable wall by the stylet is minimized.

As a result of the relative movement of the stylet 6 and sleeve 4, the stylet's pre-bent end section 18 can either be fully retracted into the sleeve 4 or deployed more or less in the position, shown in the FIG., at which the entire distal end section 18 of the stylet 6 projects beyond the distal end 10 of the sleeve 4.

When the stylet unit is a conventional double stylet combination, in which both the stylet sleeve's 4 channel and the stylet 6 have a circular cross-section, retraction of the pre-bent distal end section 18 of the stylet 6 into the straight stylet sleeve 4 (see FIG. 8a) causes the sleeve's corresponding end section to bend outward to one side (see FIG. 8b) because of the pre-tensioning force developing in the sleeve (when the stylet is retracted into the sleeve), thereby forcing the stylet end section 18 to straighten.

FIGS. 2-3 show a first embodiment of a controllable double stylet unit 22, according to the invention, which comprises a flexible, tubular stylet sleeve 24 and an inner stylet 26 movingly arranged inside the sleeve channel. The stylet sleeve 24 has a distal end section or segment 28 and a proximal end section 30. The end section is attached to a support tube 32 which makes possible coaxial movement of the stylet 26 and sleeve 24. The parts of the internal stylet 26 which protrude out of the stylet sleeve's 24 pre-bent end section 28, on the one hand, and out of the end of the holder tube 32, facing away from the sleeve's end section 30, on the other hand, have been drawn with a dashed outline for the sake of clarity. As FIG. 2 shows, the inner stylet 26 has a straight proximal end section outside the support tube 32 and a distal end section 18, forming a circular loop 18, outside the opening of the sleeve end section 28. At the tip of its pre-bent end section 18, the stylet 26 has a small end means in the form of a stop ball 20, attached to end of the stylet, which prevents inadvertent retraction of the pre-bent end section 18 too far into the sleeve's end section 28 and penetration of the surrounding electrode cable wall by the end of the stylet.

Thus, FIG. 2 shows the stylet unit 22 with the stylet end sections 28 protruding out of the sleeve 24. FIG. 3 shows the stylet unit 22 after the stylet 26 has been axially retracted the stroke distance L out of the support tube 32 and sleeve 24. The inner stylet's 26 circular, pre-bent end section 18 has accordingly been fully retracted into the sleeve's 28 end section so the end stop ball 20 is at the opening of the end section 28. In practice, "retraction" of the end section 18 into the sleeve section 28 is achieved when the stylet sleeve 24 is slid over the stylet end section 18. Since the stylet sleeve's 24 distal end section 28 is pre-bent in a direction opposite to the bend of the stylet end section 18, retraction of the stylet end section 18 into the sleeve section 28 causes both prebends to cancel out each other, enabling the stylet unit 22 to assume the straight configuration shown in FIG. 3. Thus, the "pre-tensioning force", which the stylet end section 18 generates in the sleeve end section 28 when the stylet is retracted into the end section 28, counteracts and cancels out the stylet sleeve's 24 own bending of its end section 28 in the opposite direction. For the two bending effects, exerted by the stylet sleeve's pre-bent end section 28 and the stylet's pre-bent end section 18, to cancel out each other, they must act in opposite directions on the same plane, in this instance on the plane shown in FIG. 2. So the inner stylet must be kept from rotating in relation to the surrounding stylet sleeve 24. This rotation-prevention effect is achieved when the stylet sleeve 24 and the stylet 26 insertable therein both have a non-circular cross-section. In other words, the inner stylet's cross-sectional profile must be such that the stylet is incapable of rotating in the stylet sleeve's 24 channel. For the inner stylet 26 to be able to perform the desired coaxial movement inside the stylet sleeve, some tolerance or radial play must be left between the cross-sections of the inner stylet and the stylet channel. In practice, it may be appropriate (as noted above in conjunction with examples supplied of values for the diameter of the inner stylet and its associated stylet sleeve) for the stylet and sleeve channel to be dimensioned so radial play between them amounts to at least 0.02 mm.

FIGS. 7a, 7b, 7c, 7d and 7e schematically depict some examples of cross-sectional shapes for interacting parts (longitudinal segments, areas or local sections), i.e. the inner stylet plus its surrounding stylet sleeve, the heavily exaggerated play between them designated δ in the. FIGURES. Both the inner stylet and the surrounding stylet sleeve are appropriately made of metal, preferably steel. Both the stylet sleeve 24 and the inner stylet 26 are flexible, but the sleeve's surface moment of inertia is greater than the inner stylet's, due to the prevailing geometry, so retracting the stylet end section 18 into the sleeve's end section 28 has the effect apparent in the comparison between FIG. 2 and FIG. 3. The flexural stiffnesses of the sleeve and inner stylet can and should obviously be adapted to the material(s) selected for these stylet unit components. The stylet sleeve's and Inner stylet's pre-bent end sections should therefore have curvature radii, curve lengths and flexural stiffnesses so the straightening, backward bending of the stylet sleeve, caused by the stylet, and the stylet

sleeve's own pre-bending cancel out each other when the stylet's pre-bent end section is retracted into the stylet sleeve's distal end section 28. FIGS. 9a and 9b show highly schematic and greatly exaggerated views of the way the inner stylet's and stylet sleeve's pre-bending are devised to achieve the desired straight configuration for the stylet unit's 22 end section, as shown in FIG. 9b.

FIGS. 4 and 5 show the shape of the separate inner stylet 26 and the shape of the separate stylet sleeve 24 before the stylet 26 is inserted into the sleeve to achieve the stylet unit 22 configuration shown in FIG. 2. FIG. 4 shows that the distal end section 18 of the inner stylet 26 is pre-bent with a constant bending radius ρ_{19} which is far smaller than the bending radius ρ_{28} of the pre-bent end section 28 of the stylet sleeve 24 shown in FIG. 5. Thus, the end section 28 also has a constant bending radius and, in the illustrated instance, a curve length corresponding to a radian on the order of about 40°. Since the inner stylet's pre-bent end section 18 in FIG. 4 has the shape of a closed loop, the curve length in this instance obviously corresponds to more than 360°.

As FIG. 4 shows, the stylet's 26 pre-bent end section 18 changes into a straight, concluding end section with the ball 20 attached to its free end. This straight end section has a length 1 whose magnitude is selected with a view to e.g. current requirements and anatomical conditions in the body cavity in which the bent electrode cable, manipulated by the stylet unit and stylet sleeve's end section 18, is to be anchored. The straight end section typically has a length ranging from 5 to 20 mm to facilitate electrode maneuvering. However, much longer stylet end sections can be used in other stylet unit applications.

As FIGS. 7a, 7b. 7c and 7d show, the interacting parts or segments of the stylet and sleeve channel with non-circular cross-sections can have identical cross-sections and be devised e.g. as concentric ovals, ellipses or regular polygons with rounded corners. The stylet sleeve 24 can obviously even have a circular-cylindrical exterior, i.e. have a completely circular cross-sectional profile for its exterior, as shown in FIG. 7e.

In its fully deployed position outside the stylet sleeve's 28, the stylet's 26 pre-bent end section 18 has the circular loop shape shown in FIGS. 2 and 4, but the end section's 18 curve length can also be limited to a radian less than 360°, or greater than 360°. However, it may be suitable in many instances for the inner stylet's 26 distal end section 18 to have a U-shaped or J-shaped bend when the end section is deployed outside the stylet sleeve.

The above-described stylet unit 22 is especially designed for introduction into an electrode cable 34, hollow throughout its length, of the kind used with a heart stimulator for transmitting electrical impulses from the heart stimulator to a contact electrode 36, anchored in a cavity of the heart, on the distal end of the electrode able. One example of such an electrode cable 24 with an inserted internal stylet unit is shown in FIG. 6. When the stylet unit is inserted into the electrode cable, it is advantageous for the stylet unit 22 to have the straight shape shown in FIG. 3. The stylet unit 22 is inserted into the very flexible and "floppy" electrode cable in order to stiffen the cable during its advancement through a suitable vein to the heart. In the introduction into and anchoring of the electrode cable's contact electrode 26 in e.g. the heart's right atrium, the stylet unit is also used to achieve an appropriate curvature for the electrode cable's end section on whose end the contact electrode 36 is located. This bending of the electrode cable's end section is achieved when the shape of the stylet unit is changed from the straight configuration shown in FIG. 3 to the shape in which both the stylet sleeve 24 and the inner stylet have bent end sections, as shown in FIG. 2. But since the electrode cable is much thicker than the distal end section 18 of the stylet 26, the stylet is incapable of bending the electrode cable into a loop and instead gives the distal end of the electrode cable a fish hook-like shape, as shown in FIG. 6. The cable's distal end section, equipped with the contact electrode 36, then runs essentially parallel to the straight section 38 of the cable, towards the proximal end of the cable.

Referring to FIGS. 10-15, the stylet unit according to the invention will now be exemplified with several alternative embodiments in which the stylet sleeve channel and the associated inner stylet do not have a non-circular cross-sections across the stylet unit's entire length.

The background of these alternative embodiments is as follows:

In the use of a stylet unit in which both the stylet sleeve channel and its associated, moving inner stylet do not have a non-circular cross-section along the stylet unit's entire length, certain problems can develop because of increased friction between the styler and stylet sleeve channel, especially in instances in which the entire stylet unit is subjected to extensive bending. When a hollow electrode cable, with an inserted stylet unit, is to be introduced into the heart via the venous system, different parts or sections of the electrode cable will be bent to different degrees, as is shown in a schematic depiction, in FIG. 10, of an electrode cable 50 worn an hand-operated guide means 52 for the stylet unit inserted into the electrode cable. The guide means 52 is located at the proximal end of the electrode cable 50. Movement of the stylet unit's inner stylet (not shown here) in relation to its surrounding stylet sleeve is performed by manual movement of the guide means' sleeve part 54 in relation to the tubular part 56 of the means. A practical problem caused by the increased friction occurring in the electrode cable's bending is that the use of excessive force may be necessary in order to operate the guide means 52.

The increase in friction in the stylet unit is because of elevated contact pressure between the stylet and interior of the sleeve channel when the stylet buckles in-

side the stylet sleeve and because of other friction phenomena. However, the buckling phenomenon can be avoided when the stylet sleeve channel and the stylet have a rotation-symmetrical cross-section instead of a non-symmetrical (non-circular) cross-section at the points at which the electrode cable must be bent.

This effect can be achieved when the stylet sleeve channel or the internal stylet have a circular cross-section in the bent areas. In the first instance, the stylet sleeve channel is devised with non-circular cross-section only at the location to be compensated for the flexural moment the stylet exerts on the surrounding stylet sleeve when the stylet is inserted into the sleeve.

FIGS. 11 and 12 show a first alternative embodiment of the sleeve and attendant stylet. The stylet sleeve, generally designated 58, consists in this instance of a longer first sleeve part 60 and a shorter second sleeve part 62. The sleeve part 60 is a circular, cylindrical tube with a circular cross-sectional profile for both the interior of the tube channel and the exterior of the tube. The sleeve part 62 also has a circular, cylindrical exterior with a circular cross-sectional profile, the channel's cross-sectional profile being non-circular in this instance.

The inner stylet, generally designated 64, for the sleeve 58 according to FIG. 11 is equipped with a circular, pre-bent distal end section 66 of about the same type shown in FIG. 4. In this instance, the stylet 64 has a non-circular cross-section with the dimensions 0.19 mm x 0.30 mm.

FIG. 13-14 show alternative embodiments of a stylet sleeve with an attendant inner stylet in an alternative stylet unit according to the invention.

In this instance, the stylet sleeve, generally designated 68, as shown in FIG. 13, is an externally circular, cylindrical tube but whose internal channel has a non-circular cross-section. Here, the diameter of the sleeve 68 is 0.416 mm, whereas the non-circular cross-section of the sleeve's internal channel is envisaged as being 0.24 mm x 0.34 mm.

The inner stylet, generally designated 70, for the stylet sleeve, generally designated 68, according to FIG. 13 and shown in FIG. 14, consists in this instance of a shorter first stylet section 72 with a non-circular cross-section, a longer second stylet section 74 with a circular cross-section and a pre-bent, distal end section 76 with a non-circular cross-section. In this instance, the stylet sections 72 and 76 are envisaged as both being 0.20 mm x 0.31 mm, whereas stylet section 74 is circular and cylindrical with a 0.19 mm cross-sectional diameter.

A stylet 70 of the kind shown in FIG. 14 can be made in a continuous process by means of the work stages illustrated in 15a, 15b. 15c and 15d.

According to FIG. 15a, a circular, cylindrical stylet with a diameter of about 0.30 mm is made first.

According to FIG. 15b, a pair of separate stylet segments, 540 mm long with a cross-sectional diameter of 19 mm, is then processed (ground down).

According to FIG. 15c, the parts of the stylet which still have a diameter of 0.30 mm are then worked until these parts have a non-circular cross-section with the dimensions 0.19 mm x 0.30 mm. The finished stylet is then cut off at points S1-S1 and S2-S2 respectively.

According to FIG. 15d, the distal end of the stylet 70 made this way is equipped with a small end ball 20, and, finally, the distal end section 76 of the stylet is given its circular loop shape, as shown, in FIG. 14.

The alternative stylet sleeves 80 shown in FIGS. 16 and 17 both have a sideways pre-bent distal end section 82 and 82', respectively. The end section 82 has a non-circular channel cross-section over its entire length, whereas the end section 82' has two longitudinally spaced longitudinal sections or portions 88 and 90 having non-circular channel cross-section. Of the stylet sleeve according to FIG. 16 as well as FIG. 17 the straight stylet sleeve part 81 to the left (as seen in FIGS. 16 and 17) of the pre-bent end section 82 and 82', respectively, has a circular channel cross-section. The inner stylet wire 84, shown in FIG. 18, which can be used either in the stylet sleeve according to FIG. 16 or in the sleeve according to FIG. 17, has a circular cross-section in the stylet wire part 85 to the left of its distal end section 86, which fits into the channel in the matching stylet sleeve's 80 distal, pre-bent end section 82 and 82', respectively. The inner stylet's end section 86 has a non-circular cross-section corresponding to the non-circular channel cross-section of the pre-bent distal end section 82 and 82', respectively. The length of the distal stylet end section 86 is twice the length of the sleeve's end section 82 and 82', respectively.

Thus, in the embodiments according to FIGS. 16-17 the stylet sleeve 80 has non-circular channel cross-section only in its distal end section 82 and 82', respectively, which preferably has a length corresponding to the inner stylet's 84 intended travel length. The remaining part of the sleeve 80, i.e. the sleeve part 81, has a circular channel cross-section. The inner stylet wire 84 has a non-circular cross-section only in its distal end section 86 the length of which is at least twice the travel length of the inner stylet wire. The remaining part 85 of the inner stylet 84 has a circular cross-section.

One advantage of this stylet wire embodiment (see FIG. 19) is that the stylet wire part having a circular cross-section is not turned down from a wire having a non-circular cross-section, but is made in another way (the diameter of the circular part 85 is larger than the height h of the stylet wire's non-circular section 86 but smaller than the width b of the wire's non-circular section). This results in a very good stiffness (rigidity) in the proximal end portion of the stylet wire although it has a circular cross-section. Dimensionally this embodiment implies that the styler wire's non-circular section 86 should have a length being at least twice the travel length of the part of the stylet wire 84 deployable outside the stylet sleeve 80, so that this deployable part will be able to show a length corresponding to the intended

travel length.

Claims

1. A stylet unit which can be inserted into an elongate means with an internal, longitudinal channel, such as an electrode cable for a heart stimulator, a coronary catheter or some other type of hollow, oblong instrument, in order to stiffen the channel-equipped means and bend a distal end section of same, said stylet consisting of a double stylet combination (22) comprising a flexible, tubular stylet sleeve (24, 58, 68) and an inner stylet (26, 64, 70), being displaceably arranged in the stylet sleeve channel and having a distal end section (18, 66, 76) pre-bent to one side, **characterized** in that the stylet sleeve (24, 58, 68) has at least one longitudinal section (62, 68) or segment in which the sleeve's channel has a non-circular cross-section, and the inner stylet (24, 64 70), which is displaceable in the styler sleeve channel, has at least one longitudinal section (72, 76) with a non-circular cross-section, the shape of the profile of the stylet's non-circular cross-section being such, in relation to the profile of the stylet sleeve's non-circular channel cross-section, that the stylet (26, 64, 70) is kept from rotating, in relation to the surrounding sleeve (24, 58, 68), in the parts of the sleeve in which both the stylet and sleeve channel have interacting non-circular cross-sections.

2. A stylet unit according to claim 1, **characterized** in that the stylet sleeve (58) has a first longitudinal section (60) in which the channel has a circular cross-section, followed by a second longitudinal section (62) in which the channel has a non-circular cross-section, and the inner stylet (64) has a non-circular cross-section over virtually its entire length.

3. A stylet unit according to claim 1, **characterized** in that the stylet sleeve's (68) channel has a non-circular cross-section over virtually its entire length, and the inner stylet (70) has a first longitudinal section (72) with a non-circular cross-section, followed by a second longitudinal section (74) with a circular cross-section, followed by a third longitudinal section (76) with a non-circular cross-section.

4. A stylet unit according to claim 1, **characterized** in that the stylet sleeve's (24) channel and the inner stylet (26), which is displaceable within the channel, both have a non-circular cross-section over virtually their entire length, whereby the stylet (26) is prevented from rotating in relation to the surrounding sleeve (24) along the stylet unit's entire length.

5. A stylet unit according to any of claims 1-4, **characterized** in that the stylet sleeve (24, 58, 68) has a distal end section (28) which is pre-bent in a first lateral direction in relation to the stylet unit (22), whereas the inner stylet's (26, 64, 70) distal end section (18, 66, 76) is pre-bent in the opposite lateral direction.

6. A stylet unit according to claim 5, **characterized** in that the stylet sleeve's (24, 58, 68) distal end section (28) is pre-bent with a virtually constant bending radius (ρ_{28}), and this pre-bent end section has a curve length corresponding to a radian less than 90°, preferably not more than 45°.

7. A stylet unit according to claim 5 or 6, **characterized** in that the inner stylet's (26, 64, 70) distal end section (18, 66, 76) is pre-bent with a virtually constant bending radius (ρ_{18}) which is much less than the bending radius (ρ_{28}) of the stylet sleeve's (24, 58, 68) pre-bent distal end section (28), and the stylet's pre-bent distal end section (18, 66, 76) has a curve length corresponding to at least 360°, so the end section forms a closed loop.

8. A stylet unit according claims 5-7, **characterized** in that the stylet sleeve's (24, 58, 68) and inner stylet's (26, 64, 70) pre-bent end sections (28; and 18, 66, 76 respectively) have curvature radii, curve lengths and flexural stiffnesses which counteract and cancel out the bending by the stylet of the stylet sleeve and the stylet sleeve's own pre-bending when the stylet's pre-bent distal end section (18, 66, 76) is completely enclosed in the stylet sleeve's distal end section (28), so the stylet unit (22) accordingly displays a straight configuration.

9. A stylet unit according to any of claims 4-8, **characterized** in that the inner stylet's (26, 64, 70) non-circular cross-sectional profile is the same as the non-circular cross-sectional profile of the stylet sleeve's (24, 58, 68) channel, the stylet and the sleeve channel thereby being dimensioned so play (δ) or tolerance between them amounts to at least 0.02 mm.

10. A stylet unit according to claim 9, **characterized** in that the stylet's (26, 64, 70) non-circular cross-section and the sleeve channel's cross-section are devised as concentric ovals, ellipses or regular polygons with rounded corners.

11. A stylet unit according to any of claims 5-10, **characterized** in that the distal end section (18, 66, 76) of the stylet has a U-shaped or J-shaped bend when the stylet's pre-bent end section (18, 66, 76) is fully deployed outside the stylet sleeve's (24, 58, 68) distal end section (28).

12. A stylet unit according to claim 1, **characterized** in that the stylet sleeve (80) has, over a distal end section (82;82'), at least one longitudinal section in which the channel has a non-circular cross-section, and the inner stylet (84) has a non-circular cross-section over a distal end section (86) having a length which is greater, preferably at least two times greater, than the length of the sleeve's distal end section (82;82').

13. A stylet unit according to claim 12, **characterized** in that in the stylet sleeve's (80) entire distal end section (82) the channel has a non-circular cross-section.

14. A stylet unit according to claim 12, **characterized** in that in the stylet sleeve's (80) distal end section (82') the channel has a non-circular cross-section in two or more spaced apart longitudinal sections (88, 90).

15. A stylet unit according to any of claims 12-14, **characterized** in that over its distal end section (82;82') the stylet sleeve (80) is pre-bent in a first lateral direction, and this pre-bent end section has a length which is at least approximately equal to the inner stylet's (84) intended travel length within the channel of the sleeve (80), and the inner stylet's distal end section (86) with a non-circular cross-section has a length which is at least approximately twice the length of said travel.

16. An elongate, tubular means, devised as a hollow electrode cable (34) **characterized** in that a stylet unit (22; 58, 64; 68, 70) according to any of the preceding claims is inserted into said tubular means.

Fig.1

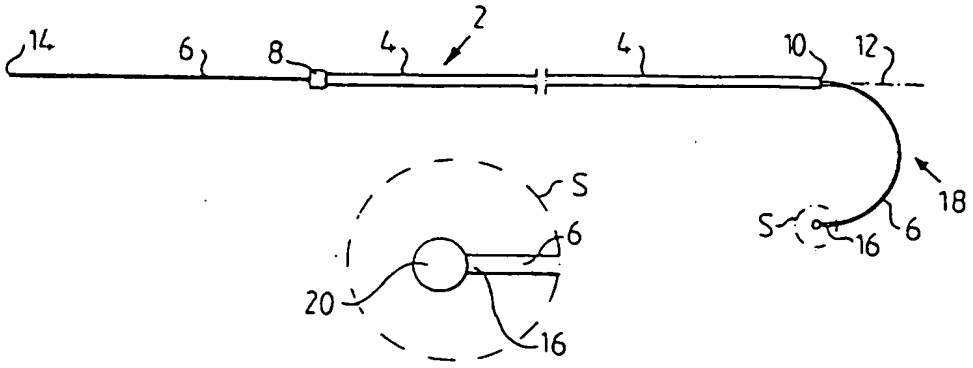


Fig.2

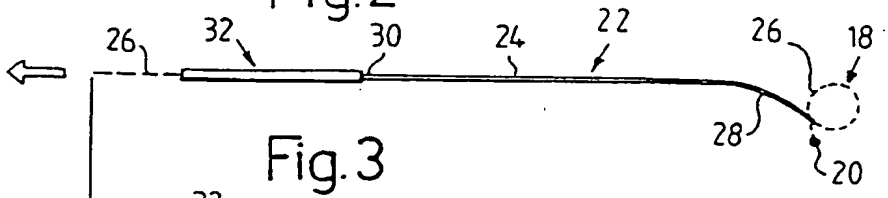


Fig.3

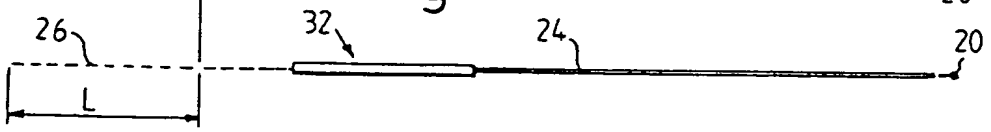


Fig.4

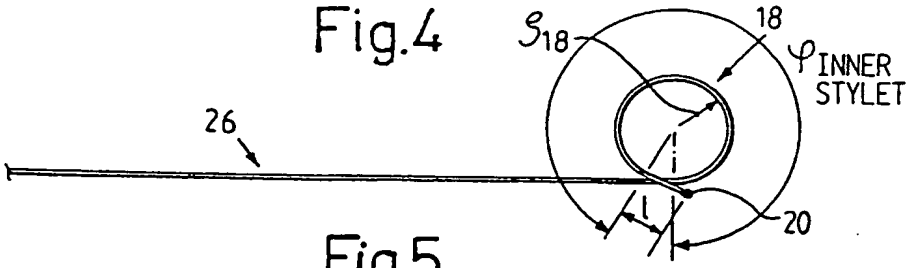


Fig.5

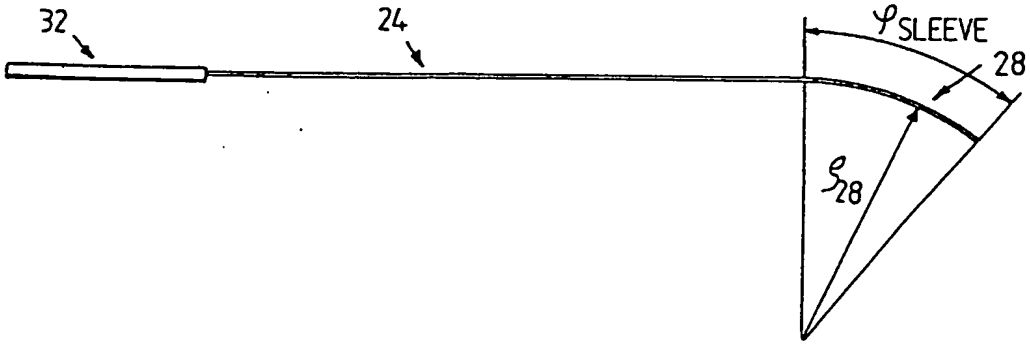


Fig.6

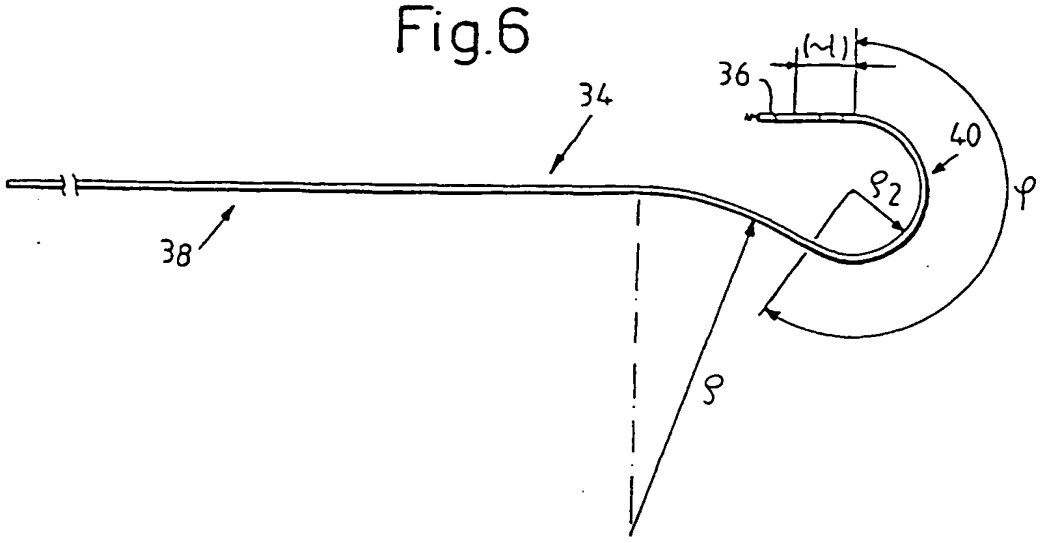


Fig.7a

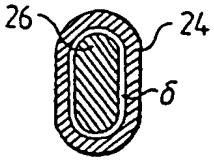


Fig.7b

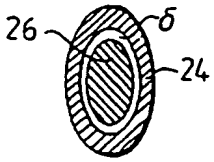


Fig.7e

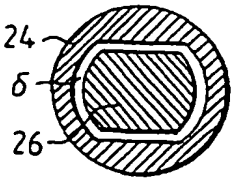


Fig.7c

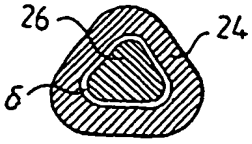


Fig.7d

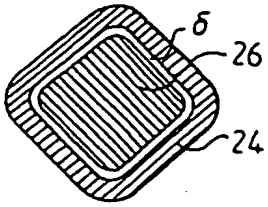


Fig.8a

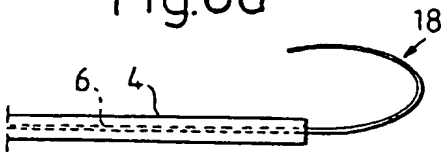


Fig.8b

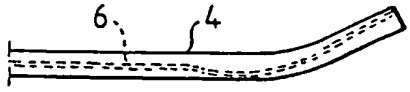


Fig.9a

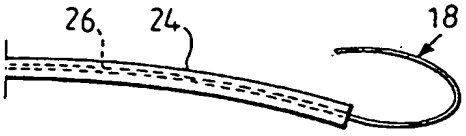


Fig.9b

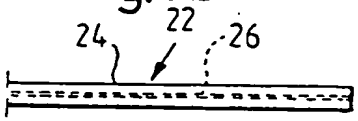


Fig.10

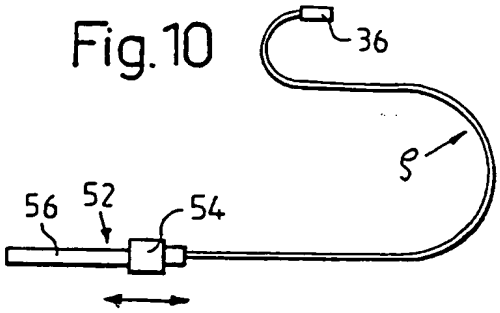


Fig.11

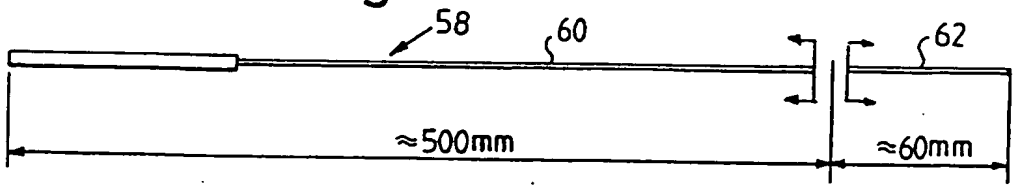


Fig.12

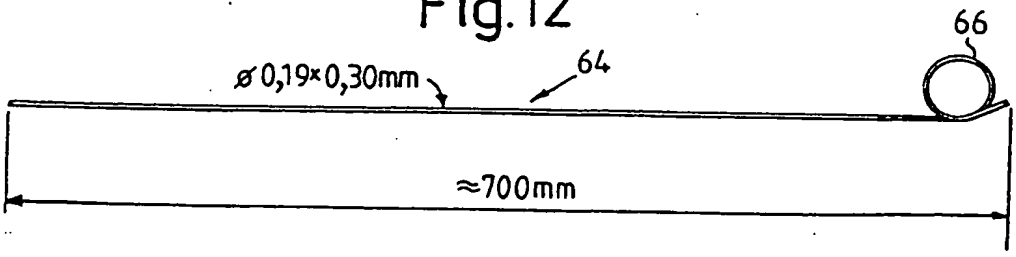


Fig. 13

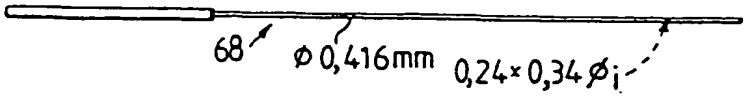


Fig. 14

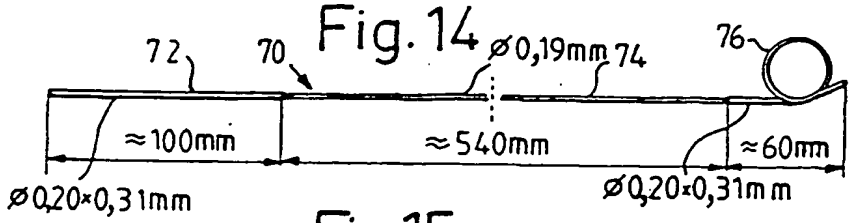


Fig. 15a

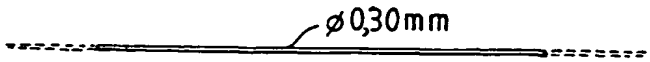


Fig. 15b

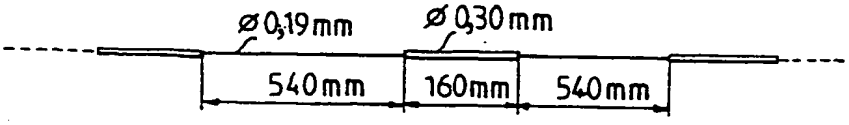


Fig. 15c

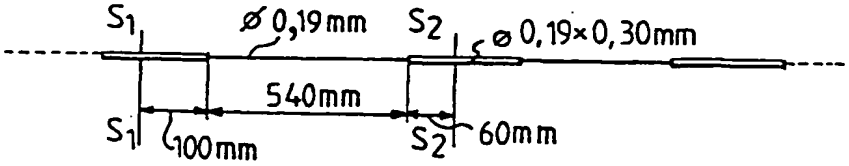


Fig. 15d

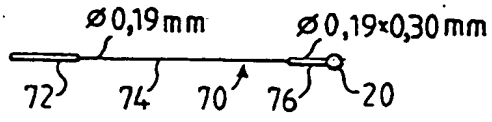


Fig. 16

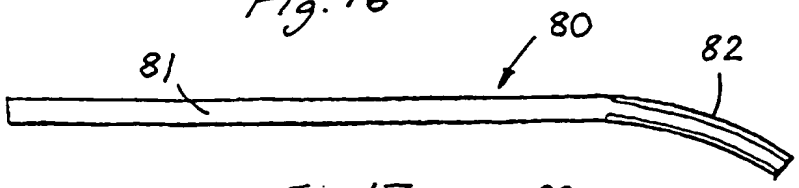


Fig. 17

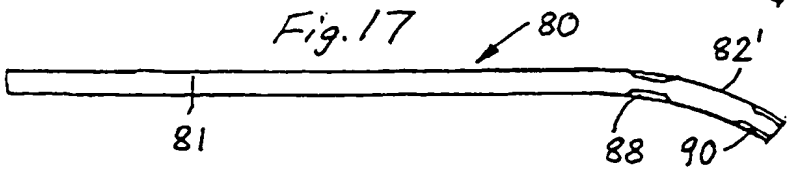
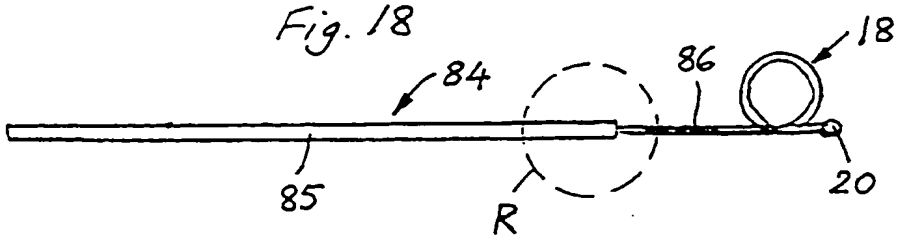


Fig. 18



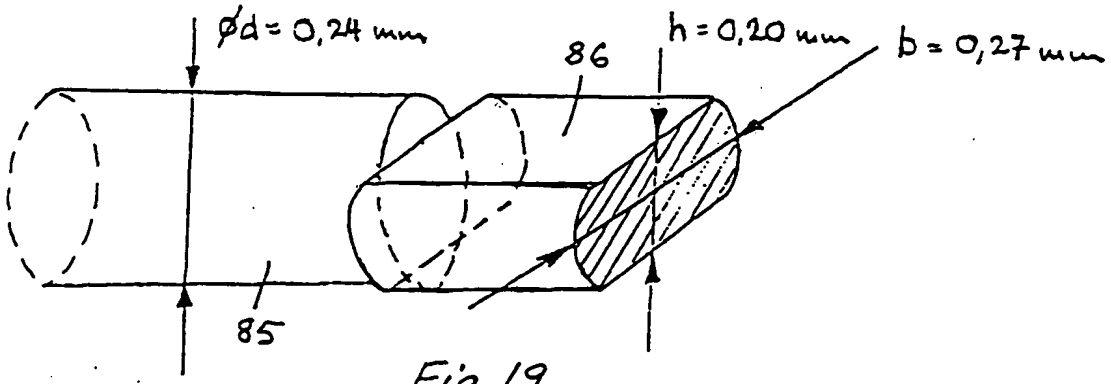


Fig. 19